

# SCORAD III trial summary v4.0

## SCORAD III: A randomised phase III trial of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression.

<b>Sponsor:</b> University College London: UCL/09/0199	<b>ISRCTN:</b> ISRCTN97108008
<b>Funder:</b> Cancer Research UK: CRUK/06/034	<b>Design:</b> A multicentre, randomised phase III trial.
<b>Overall aim:</b> To show that ambulatory status using 8Gy in 1 fraction is no worse than with 20Gy in 5 fractions for patients with metastatic spinal cord compression (SCC).	
<b>Primary endpoint:</b> <ul style="list-style-type: none"><li>Ambulatory status at 8 weeks from day 1 of treatment compared to randomisation</li></ul>	
<b>Secondary endpoints:</b> <ul style="list-style-type: none"><li>Recovery of and time to ambulation</li><li>Ambulatory status at 1, 4 and 12 weeks compared to randomisation (where available)</li><li>Maintenance of ambulatory status</li><li>Bladder and bowel function at 1, 4, 8 and 12 weeks from day 1 of treatment compared to randomisation</li><li>Adverse events using RTOG and CTCAE v.4.02 at 1, 4, 8 and 12 weeks from day 1 of treatment</li><li>Quality of life measured using the EORTC QLQ-C30 questionnaire at 1, 4, 8 and 12 weeks from day 1 of treatment compared to randomisation</li><li>Further treatment and SCC retreatment up to 12 months after randomisation</li><li>Duration of care in hospital, hospice, nursing home or home</li><li>Preferred place of care</li><li>Overall survival at 12 weeks and 12 months</li></ul>	
<b>Target accrual:</b> 580 patients	
<b>Eligibilities:</b>	
<b>Inclusion criteria:</b> <ul style="list-style-type: none"><li>Decision to treat made no more than 48 hours prior to treatment of spinal cord or cauda equina (C1 to S2) compression, based on a full spinal MRI or CT scan confirming compression carried out no more than one week prior to treatment.</li><li>Single site of compression or multiple sites that can be treated within a single radiation treatment field</li><li>Histologically or cytologically confirmed malignant disease, or for prostate tumours a serum PSA &gt;100 ng/ml at any point prior to randomisation (if biopsy done or planned but results not yet available patients may be entered provided all other inclusion and exclusion criteria are met. Biopsy results must be submitted on the relevant CRF page as soon as they are available)</li><li>Life expectancy &gt;8 weeks</li><li>Age ≥18 years</li><li>Able to give written informed consent</li><li>Willing and able to complete assessment forms</li></ul>	
<b>Exclusion criteria:</b> <ul style="list-style-type: none"><li>Patients for whom surgery or chemotherapy treatment is more appropriate</li><li>Patients who are known to be pregnant</li><li>Patients with multiple myeloma, lymphoma, leukaemia or glioma</li><li>Patients undergoing purely prophylactic treatment in the absence of radiological spinal cord or cauda equina compression</li><li>Patients whose spinal compression site has been treated previously with radiotherapy</li></ul>	
<b>Planned sites:</b> ~50	
<b>Target Countries:</b> United Kingdom, Australia and New Zealand	
<b>Treatment summary:</b>	
<b>Arm 1:</b> Multiple fraction radiotherapy 20Gy/5f	
<b>Arm 2:</b> Single fraction radiotherapy 8Gy/1f	
<b>Anticipated duration of recruitment:</b> 4 Years	
<b>Duration of patient follow up:</b> 12 months	
<b>Definition of trial end:</b> 12 months post randomisation of last patient or the death of the last surviving patient, whichever event occurs first	

# SCORAD III trial schema v4.0

